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10/611,775	06/30/2003	John C. Hill	084.0004X1 (FLORA.1300)	1915
77037 7590 08/06/2010 Ingrassia Fisher & Lorenz, P.C. (FLORATECH) 7010 East Cochise Road Scottsdale, AZ 85253-1406				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
08/06/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ifllaw.com

### Office Action Summary

**Application No.**

10/611,775

**Applicant(s)**

HILL ET AL.

**Examiner**

Isis A. Ghali

**Art Unit**

1611

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35, 36, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 36, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date 04/27/2010
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 10/09/2010, and IDS filed 04/27/2010.

Claims 1-34, 37 and 40 have been canceled. Claims 35, 36, 38, and 39 are pending and included in the prosecution.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/09/2010 has been entered.

#### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 35, 36, 38 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 12/203,004. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant

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application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: composition comprising saponified jojoba oil fraction and non-saponified jojoba oil fraction. The present claims anticipate the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 35, 36, 38 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 12/080,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: composition comprising saponified jojoba oil fraction and non-saponified jojoba oil fraction. The present claims anticipate the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 35, 36, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed 04/09/2010 introduced new matter. Claim 35 recites "totaling 100 percent by weight from saponified jojoba oil". This is new matter because nowhere applicant disclosed this limitation. Claim 38 recites "at least 18 carbons". This is new matter because in page 14 line 11 applicants disclosed "from C<sub>18</sub> to C<sub>24</sub>". Claim 38 as amended has no upper limit to the number of carbons that is limited by the specification to 24 carbons. If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

7. Claims 35, 36, 38, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The present claims are drawn to

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method of preparing a topical formulation including the step of "obtaining a composition" and the step "of neutralizing a gelling agent using said composition". The present specification failed to provide guidance or describe neutralizing gelling agent using the claimed composition. The examples in the present specification used trade name products of jojoba oils in cosmetic compositions, and not the instant composition. It is not known if the trade name products are produced by the instantly claimed method and contains the same ingredients in the same amounts. In other words, the examples of the present specification do not teach the claimed method for preparing topical composition using the claimed steps and ingredients. No guidance is provided regarding using the claimed composition to neutralize gelling agent, rather applicants used trade names products. Claims employing limitation at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. Applicants were not in possession of the claimed subject matter at the time of the invention.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F. 3d 1559, 1568 (Fed. Cir. 1997), cert denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish list or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and

Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including inter alia, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly and Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216,225 (W.D.N.Y. 2003).

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111. The invention is, for purpose of the "written description" inquiry, what ever is now claimed (see page 1117). The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 116). One cannot describe what one has not conceived. See *Fiddes v Baird*, 30 USPQ2d 1481, 1483.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed



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subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983). See MPEP 2163.06.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him. See *Genetech*, 108 F.3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 35, 36, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing regarding the gelling agent as it is not clear to the examiner if neutralizing a gelling agent is part of the claimed method or it is the use of the claimed composition?

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 35, 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over FR 2471775 ('775) as evident by O'Connor et al. "Long-chain unsaturated alcohols from jojoba oil by sodium reduction", currently provided, or as evident by Daugherty et al. "Industrial raw materials of plant origin", currently provided", and in view of US 6,280,746 ('746).

### **Applicant Claims**

Applicants' currently amended claims 35 is directed to a method for preparing a topical formulation, said method comprising the steps of: obtaining a composition comprising alkali salts of jojoba fatty acids and non-polar unsaponifiables totaling 100 percent by weight from saponified jojoba oil, the saponified jojoba oil comprising at least 6 weight percent non-polar unsaponifiables prior to saponification; and neutralizing a gelling agent in said topical formulation with an effective amount of said composition.

Currently amended claim 38 further recite the alkali salts of jojoba fatty acids present in an amount of about 55 percent by weight of the composition and long carbon chain unsaponifiable material present in an amount of about 45 percent by weight of the composition, wherein said long carbon chain unsaponifiable material comprising at least 18 carbons in length.

**Determination of the Scope and Content of the Prior Art**  
**(MPEP §2141.01)**

FR '775 teaches cosmetic composition comprising mixture of jojoba oil and sunflower oil, and from 20-40% unsaponifiables oils fractions (page 4, 3<sup>rd</sup> paragraph). The unsaponifiable fraction includes residual part of saponifiable components and unsaponifiable fraction, with the **unsaponifiable** ingredients is **greater than 40%** (paragraph bridging pages 4 and 5). FR '775 teaches composition comprising saponifiable and unsaponifiables fractions obtained from vegetable oils and suggested jojoba oil. The cosmetic composition can be in the form of gel (last paragraph of page 5). Examples 3-5 and 7 showed composition comprising gelling agent Caropol 940, which is an acidic gelling agent. The reference teaches that unsaponifiables display interesting dermatological properties and used in cosmetics (page 3, 5<sup>th</sup> paragraph).

Jojoba oil taught by FR '775 contains non-saponifiable fraction of fatty alcohol having C<sub>20</sub>-C<sub>22</sub> carbons as evident by O'Connor who teaches that hydrolysis of jojoba oil provides alcohol of high unsaponifiable value and low free fatty acids (see the entire document, especially page 381, left column). This fact is also evident by the teaching of Daugherty who teaches that jojoba oil (*Simmondsia chinensis*) contains fatty acids (saponifiable) having C<sub>16</sub>-C<sub>18</sub> carbons and 37.62-48.3% fatty alcohols (non-saponifiable) having C<sub>20</sub>-C<sub>22</sub> carbons (see table 1 at page 297 and 299, left column). The teaching of Daugherty implies that jojoba oil contains 62-38-51.7% saponifiable fatty acids.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Although FR '775 teaches composition comprising saponifiable and unsaponifiables fractions obtained from vegetable oils and suggested jojoba oil, however, the reference does not explicitly teach pretreatment, such as hydrolysis of the oil. Jojoba oil contains both saponifiable and non-saponifiable fractions as evident by the teachings of O'Connor and Daugherty,

US '746 teaches cosmetic composition comprising jojoba oil (abstract). When applied to the skin, the cosmetic composition comprising jojoba oil prevents and retains natural moisture level of the skin (col.8, lines 18-24). The composition comprising jojoba oil esters from the trade name Floraesters-15, 20, 30, 60 70 (col.8, lines 35-40). The reference disclosed that jojoba oil can be catalyzed, i.e. hydrolyzed, using alkali metal hydroxide, as applicants had done (col.3, lines 53-60). The reference disclosed gel comprising Carbopol (example 2). The Floraester disclosed by the reference are expected to have salt of saponifiable jojoba fatty acids and unsaponifiable fractions of jojoba oil, and expected to comprise at least 6% long chain carbon material prior to hydrolysis, since applicants exemplified and practiced their invention using such trade name product. Hydrolyzed jojoba esters are produced using potassium hydroxide, and therefore they are alkaline and will display the property of neutralizing acidic gelling agent.

**Finding of Prima Facie Obviousness Rational and Motivation**

**(MPEP §2142-2143)**

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gel cosmetic composition comprising saponifiable and unsaponifiable oil fractions as taught by FR '775 as evident by O'Connor or Daugherty, and select jojoba oil because it is suggested by FR '775 and because O'Connor and Daugherty teach that jojoba oil consisting of both saponifiable fatty acids and non-saponifiable fatty alcohol, and further one would use jojoba oil hydrolyzed by alkali metal hydroxide to provide salts of jojoba fatty acids as taught by US '746. One would have been motivated to do so because US '746 teaches that cosmetic composition comprising hydrolyzed jojoba oil when applied to the skin prevents and retains natural moisture level of the skin. One would have reasonably expected formulating gel cosmetic composition comprising hydrolyzed jojoba oil comprising saponifiable and unsaponifiable fractions wherein the composition prevents and retains natural moisture level on application to the skin.

Regarding the claimed amounts of saponifiable and non-saponifiable fractions, the prior art teaches 37.62-48.3% fatty alcohols (non-saponifiable) and 62-38-51.7% fatty acids (saponifiable). Therefore, the amounts and corresponding ratio overlaps with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

14. Applicant's arguments filed 04/09/2010 have been fully considered but they are not persuasive.

Regarding Arquette reference (US '746), by the same assignee of the present application is qualified as prior art because it has different inventive entity and it does not disclose all the elements of the subject matter of the present method. See *In re Chu* (CAFC) 36 USPQ2d 1089 (1995).

Applicants argue that FR '775 describes and claims specific composition, namely jojoba oil and sunflower oil combined with an unsaponifiable fraction extracted from soy and avocado oil. The cosmetic oil of FR '775 does not contain an unsaponifiable fraction extracted from jojoba oil. There are no jojoba hydrolysates in FR '775 and no suggestion for their inclusion. Therefore, regardless of whether Arquette describes hydrolyzed jojoba esters, the combination is inappropriate.

In response to this argument, it is argued that if FR '775 had disclosed hydrolyzed jojoba oil, it would have been an anticipatory reference. FR '775 however teaches composition comprising saponifiable and unsaponifiables fractions obtained from vegetable oils and suggested jojoba oil. The reference teaches that unsaponifiables display interesting dermatological properties and used in cosmetics.

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Further, jojoba oil naturally contains both saponifiable and unsaponifiable fractions as evident by O'Connor and Daugherty. Since FR '775 desired to have both fractions in a cosmetic composition, and the art recognized the presence of both fractions in jojoba oil and further recognized hydrolysis of jojoba oil is advantageous to the skin taught by US '746, then the combination of the references are proper.

Applicants argue that Arquette does not describe the products of saponified jojoba oil or a composition comprising a mixture of about 55 percent by weight alkali salts of jojoba fatty acids and about 45 percent by weight non-polar unsaponifiables (Claim 38) totaling 100 percent by weight (Claim 35) as now claimed. Arquette instead describes alcoholysis.

In response to this argument, it is argued that the claimed percent of saponifiable to non-saponifiable fractions is the natural percentage of fatty acid to fatty alcohol as present in natural jojoba oil as evident by the article by O'Connor and the article by Daugherty, both are now of record. It is further argued that US '746 teaches hydrolysis of jojoba oil using metal alkali in col.3, lines 58-60. US '746 teaches cosmetic composition comprising jojoba oil ester from the trade name Floraesters-15, 20, 30, 60 70, which applicant used in their examples instead of using the claimed composition. Trade name products should have the same fractions of saponified and unsaponified.

Therefore, the examiner believes that the combination of the references is proper and would have rendered the present invention prima facie obvious. The fact that



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applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraidia v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is

more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

Finally, it is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

### ***Correspondence***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

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0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/  
Primary Examiner, Art Unit 1611

IG